Pharmacotherapeutic report, summary

Rilpivirine-emtricitabine-tenofovir disoproxil (Eviplera®)
for the indication 'infection with HIV-1'

Approved on 26 March 2012 by the Medicinal Products Reimbursement Committee (CFH)

Medicine. Emtricitabine 200 mg, rilpivirine (hydrochloride) 25 mg and tenofovir disoproxil (fumarate) 245 mg; film coated tablet

Registered indication. "the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml."

Posology. 1 tablet daily.

Working mechanism. Emtricitabine, rilpivirine and tenofovir disoproxil inhibit the activity of reverse-transcriptase, the HIV-enzyme that converts viral RNA into viral DNA. As a result the drug interrupts virus replication. The combination has a synergistic effect.

Summary of the therapeutic value

Intended effects. In adult, previously untreated patients with an HIV-infection and a virus concentration ≤ 100,000 copies/ml, the use of rilpivirine does not lead more frequently to a virologic response than the use of efarivenz, both given in combination with emtricitabine and tenofovir. The reliability of the underlying sub-group analysis is uncertain. The outcomes on CD4-cell number or HIV-related infections are unknown. In the event of virologic failure of the rilpivirine combination, cross-resistance to NRTIs occurs more frequently than with virologic failure of the efavirenz combination.

Unintended effects. In relatively short-term studies, the use of the rilpivirine combination Eviplera® causes less frequent and less severe side effects than the efavirenz combination Atripla®.

Experience. Experience with Eviplera® is limited, while sufficient experience has been obtained with Atripla®.

Applicability. Eviplera® and Atripla® are registered for different groups. Neither of the drugs may be used on children, nor in cases of severe renal or hepatic function disorders. Interactions with other medicines are known to occur with both drugs.

Ease of use. Eviplera® and Atripla® are both taken once daily in tablet form. This means that the ease of use is the same.

Final conclusion. For the treatment of adult, therapy-naive patients infected with HIV-1 and with a virus concentration ≤ 100,000 copies/ml, the therapeutic value of the combination rilpivirine-emtricitabine-tenofovir (Eviplera®) is comparable with that of the combination efavirenz-emtricitabine-tenofovir (Atripla®).

*The original text of this **CFH Report** of CVZ was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of CVZ's CFH-report.*
Furthermore, CVZ points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.